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Low-dose fotemustine for recurrent malignant glioma: a multicenter phase II study.

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Abstract

Fotemustine at the conventional dose of 100 mg/m² is an active treatment for recurrent malignant gliomas (RMGs). However, it is associated with a relevant incidence of severe myelotoxicity, which is not justified in the palliative setting of this disease. This study was conducted to address whether administration of fotemustine at 60 mg/m² (induction) followed by 75 mg/m² (maintenance) would preserve clinical activity with the advantage of improved tolerance. Forty patients with RMGs pretreated with ≤ 2 lines of chemotherapy were enrolled. Median age was 57 years (26-80) and median Karnofsky performance status was 80 (60-100). Thirty-one patients (77.5%) had tissue available for analysis of the O(6)-methylguanine methyltransferase (MGMT) gene promoter which was found to be methylated in 14 cases (45%). Overall, 8 partial responses (20%) and 13 disease stabilizations (32.5%) were observed for a disease-control rate of 52.5%. At 6 months, 21% of patients were free from progression. Grades 3 and 4 platelet and white blood cell toxicity occurred in $\leq 10\%$ of patients, and no patients discontinued treatment because of toxicity. No significant difference was observed for disease control rate between methylated and unmethylated patients, although a trend toward improved progression-free survival was reported for methylated patients. Low-dose fotemustine has activity comparable with that of the full-dose regimen, therefore it should be preferred for its greater tolerability. The role of MGMT gene promoter methylation status in relation to sensitivity to fotemustine is still unclear and needs further evaluation in future clinical trials.

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